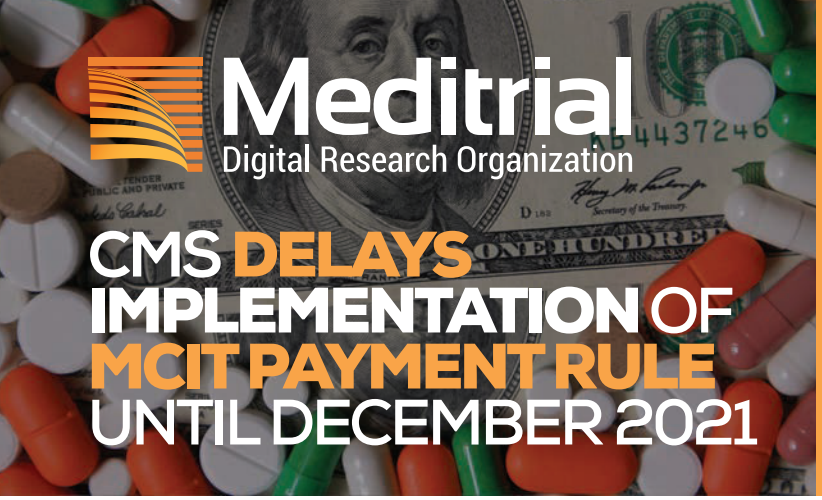

Meditrial
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CMS DELAYS IMPLEMENTATION OF MCIT PAYMENT RULE UNTIL DECEMBER 2021

The Medicare Coverage of Innovative Technology (MCIT) initiative would give breakthrough devices Medicare reimbursement **automatically on the day they are approved or cleared by FDA.**

The rule sought to establish the MCIT pathway to provide beneficiaries nationwide with **faster access** to **new, innovative technologies** designated as breakthrough devices by the FDA.

WHY IS THIS HAPPENING?

The regulatory changes were originally scheduled to take effect on March 15, 2021. However, following the election of **President Biden** the January 2021 the rule became subject to a **regulatory freeze** imposed by the new administration.

On March 17, 2021, CMS published an interim final rule that delayed the effective date of the rule until May 15, 2021 and provided a new comment period to solicit additional feedback.

Now, with the considerable length of the most recent delay, CMS will have time to evaluate the planned regulatory changes and address any issues raised in stakeholders' submitted comments.

WHAT DOES IT MEAN FOR YOU?

MCIT would allow Medicare beneficiaries with **immediate national coverage** for four years for any new medical device or diagnostic test designated as a "breakthrough" and deemed safe and effective by FDA. This **immediate market access** would trigger a **requirement that CMS and manufacturers collaborate** to identify and develop any additional data necessary to make a permanent coverage decision after the initial four-year coverage period expires.

According to the proposed rule, at the end of the MCIT pathway, **a breakthrough technology** would either have a favorable National Coverage Determination (NCD), a non-coverage NCD, or coverage decided by a Medicare Administrative Contractor. This concept may well survive if the MCIT pathway in its current form is rescinded or revised.

While the MCIT proposed rule is being scrutinized and may not survive in its current form,**the issue of delayed access to FDA approved breakthrough devices** has been acknowledged by stakeholders as worthy of a solution. Therefore a new version may emerge.

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